



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,138	10/03/2003	Tanya L. Niemeyer	59673-52	3651

22504 7590 10/26/2005

DAVIS WRIGHT TREMAINE, LLP  
2600 CENTURY SQUARE  
1501 FOURTH AVENUE  
SEATTLE, WA 98101-1688

EXAMINER

EVERHART, CARIDAD

ART UNIT PAPER NUMBER

2891

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

H-2

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/679,138	NIEMEYER, TANYA L.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Caridad M. Everhart	2891	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-32 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32, 39-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### Response to Arguments

Applicant's arguments filed 8-17-2005 have been fully considered but they are not persuasive. Applicant has argued that Brasch et al does not disclose washout behavior and does not disclose the three characteristic curves and that brash only describes the leakiness of tumor microvessels. These arguments are respectfully found to be not persuasive for the following reasons. Although Brasch et al may describe the mechanism of the accumulation of contrast agent, it is believed that Brasch et al does describe the behavior recited in the claims. In Fig. 2 of Brasch et al, The time is post-contrast, so that the bottom curve would describe pleateau behavior, as the curve would start from time  $t_{sub.1}$  of applicant's Fig. 1. the second curve from the bottom in Fig. 2 of Brasch et al would correspond to persistent enhancement, and the top curve of Fig. 2 of Brasch et al would correspond to the washout behavior. The description in col. 15, lines 15-20 indicates that the increase curve describes malignancy. The description in Fig. 2 and in lines 15-20 satisfies the limitations of the description of the three behaviors, and identifying of malignancey, as Brasch et al discloses that the persistent enhancement identifies malignancy. The argument that Brasch et al does not suggest washout behavior is not found persuasive because of the reason given above; in addition, claim 1 only requires "one from the group of an imaging signal plateau behavior and an imaging signal persistent enhancement behavior ...in the event that ...tissue volume fails to exhibit an imaging signal washout behavior", so that only one of the behaviors is required. In addition, it has been argued above that

Art Unit: 2891

Brasch et al does disclose all three of the behaviors, and identifies one of the behaviors as indicating malignancy, so that malignancy can be distinguished from normal tissue.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Brasch, et al. (US 6,009,342).

Brasch, et al discloses a method of analyzing MRI data(col. 2, lines 32-34). The method is for dynamic method(col. 4, lines 40-43 and col. 5,lines 8-10). The method uses contrast(col. 6,lines 64-67). The process is automatic, as indicated by the disclosure that algorithms are used (col. 10, lines 60-65). In addition, it is conventional in the art that MRI apparatus is coupled to a computer for the acquisition and analysis of the data. The method includes the steps of determining the washout behavior (col. 10, lines 54-58), as it is disclosed that the tumors exhibit a different permeability to the contrast media from other tissues(col. 7, lines 10-22). The method is carried out on breast(col. 10, lines 7-10). The washout behavior corresponds to that the contrast media is in the interstitial space(col. 7,lines 10-20). The enhancement behavior would correspond to the interstitial space gaining contrast media. The plateau behavior would correspond to normal tissue, which would not lose contrast media at the rate of the

Art Unit: 2891

tumor tissue. The curve fitting would correspond to generating a visual indication of the behavior (col. 10, lines 60-63).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-32 and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brasch, et al as applied to claim 1 above.

Brasch et al is silent with respect to voxels and with respect to the threshold values and other settings of the method, as well as the computer readable medium.

It would have been obvious to one of ordinary skill in the art at the time of the invention that the disclosure made by Brasch et al encompasses voxels because voxels refers to the picture imaging elements, and the disclosure made by Brasch et al encompasses voxels, as the indicating of a voxel set of malignancy would correspond to the identification of the tumor tissue in the imaging process (col. 10, lines 65-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the recited settings because the settings are variables of the art which one of ordinary skill in the art would have been able to determine in order to obtain MRI images which would distinguish between background and signals and which would distinguish between the tumor and the normal tissue.

It would have been obvious to one of ordinary skill in the art at the time of the invention that the disclosure made by Brash et al includes computer readable media to carry out the steps of the process disclosed by Brasch et al because the process taught by Brasch et al includes algorithms which are carried out by the computational apparatus of the MRI apparatus(col. 10, lines 60-65).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caridad M. Everhart whose telephone number is 571-

Art Unit: 2891

272-1892. The examiner can normally be reached on Monday through Fridays 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, B. Baumeister can be reached on 571-272-1722. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
CAROL EVERHART  
PRIMARY EXAMINER

C. Everhart  
10-20-2005